DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 6, 2014

K2M, Incorporated
Ms. Nancy Giezen
Manager, Regulatory Affairs
751 Miller Drive Southeast
Leesburg, VA 20175

Re: K142016
Trade/Device Name: CAPRI Corpectomy Cage System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: October 8, 2014
Received: October 9, 2014

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142016

Device Name
CAPRI Corpectomy Cage System

Indications for Use *(Describe)*
The CAPRI Corpectomy Cage System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace collapsed, damaged, or unstable vertebral bodies due to tumor or trauma (ie. Fracture). The CAPRI Corpectomy System is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The CAPRI device may be used with allograft or autograft.

For all the above indications the CAPRI implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
CAPRI Corpectomy Cage System

Submitter
K2M, Inc.
751 Miller Drive SE
Leesburg, VA 20175

Contact Person: Nancy Giezen
Telephone: 703-777-3155
Date Prepared: 07/23/2014

Classification

Trade Name:	CAPRI Corpectomy Cage System
Common Name:	Vertebral Body Replacement Device
Regulatory Class:	Class II

Classification Name(s):
Spinal Intervertebral Body Fixation Orthosis (21 CFR 888.3060, Product Code MQP)

Predicate Device(s)
Primary Predicate:

- K2M SANTORINI Corpectomy Cage System (K111294)

Additional Predicates:

- Ulrich Obelisc (K060416)
- DePuy X-Mesh (080568)
- DePuy Surgical Titanium Mesh (K003043)

Device Description
The CAPRI Corpectomy Cage System is a hollow tube structure manufactured from Ti6Al4V ELI and Co-Cr-Mo. The cages are available in a variety of footprints, with adjustable heights and lordoses to match the patient's anatomy.

Function: The system functions as a vertebral body replacement device to used to provide structural stability in skeletally mature individuals following a corpectomy or vertebrectomy.

Intended Use
The CAPRI Corpectomy Cage System is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) to replace collapsed, damaged, or unstable vertebral bodies due to tumor or trauma (ie. Fracture). The CAPRI Corpectomy System is designed to provide anterior spinal column support even in the absence of fusion for a prolonged period. The Capri device may be used with allograft or autograft.

For all the above indications the CAPRI implants are intended to be used with supplemental internal fixation appropriate for the implanted level, including K2M Pedicle Screw and Hook Systems, and K2M Spinal Plate Systems.

Technological Comparison to Predicate(s)
The CAPRI Corpectomy Cage System was compared to predicate systems and the design features, materials and sizes were found to be substantially the same as these systems.

Non-clinical Performance Evaluation
The CAPRI Corpectomy Cage System was mechanically tested and compared to predicate devices. The CAPRI Corpectomy Cage System performed equally to or better than these systems in static compression, static torsion, dynamic compression and dynamic torsion, in accordance with ASTM F2077.

Conclusion
There are no significant differences between the CAPRI Corpectomy Cage System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.